AUG 2 6 2009

510(k) Summary of Safety and Effectiveness
SIGN Hip Construct (SHC)

Contact Information
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Classification Name:	Appliance, Fixation, Nail/Plate Combination, Multiple Components
Common Name:	Hip Fixation System
Proprietary Name:	SIGN Fin Nail
Regulatory Class:	Class II, OR, 21 CFR §888.3030
Product Codes:	KTT, HSB, HRS

Substantial Equivalence Information
The SIGN Hip Construct (SHC) is similar to the following predicate devices:

- SIGN Fin Nail (K043200)
- Holland Femoral Nail System (K983641)
- Synthes Locking Stabilization Plate (K052677)
- Howmedica Omega 3 Trochanteric Stabilization Plate (K081278)
- Howmedica T2 Recon Nail (K051624)
- Synthes CerviFix (K030377)

All of the devices listed above are similar in both their intended use and the basic concept by which they are used. The safety and effectiveness of the SHC is also based on a long history of use of this type of device in the marketplace.

Device Description
The SIGN Hip Construct (SHC) is composed of a Fin Nail Flat (Intramedullary Nail, a Rod Plate, a Rod Connector, an Interlocking Screw, two Compression Screws, a Unicortical Screw and a set of surgical instruments. Each implant component is made from stainless steel, per requirements in ASTM F138.

Indications for Use
Indications for the SIGN Hip Construct (SHC) include all peritrochanteric fractures of the hip with proper soft tissue management. This does not include femoral neck fractures and may include subtrochanteric fractures.

Performance Data
Mechanical testing was performed on the SHC implant and the results demonstrated sufficient strength for static and dynamic compressive and torsional loading modes and resistance to subsidence and expulsion. The results did not raise any issues on the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Surgical Implant Generation Network (SIGN), Inc.
% Mr. Doug Donnelly
Manager, Regulatory Affairs
451 Hills Street, Suite B
Richland, WA 99354

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Re: K083582
Trade/Device Name: SIGN Hip Construct (SHC)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, HSB, HRS
Dated: July 29, 2009
Received: August 4, 2009

Dear Mr. Donnelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buchwald

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083582

Device Name: SIGN Hip Construct (SHC)

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083582